



**UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/200,743	11/30/98	BENNEKER	F 068540002-US

HM22/0504

HOWREY & SIMON  
BOX 34  
1299 PENNSYLVANIA AVENUE NW  
WASHINGTON DC 20004-2402

EXAMINER

CHANG, C

ART UNIT

PAPER NUMBER

1625

DATE MAILED: 05/04/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
**09/200,743**

Applicant(s)  
**Benneker et al.**

Examiner  
**Celia Chang**

Group Art Unit  
**1625**



☒ Responsive to communication(s) filed on Mar 7, 2000

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-9, 11, 15, 17, 20-22, and 24-29 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1-9, 11, 15, 17, 20-22, and 24-29 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1612

### **DETAILED ACTION**

1. Claims 1-9, 11, 15, 17, 20-22 and 24-29 are pending. A response with remark filed by applicants in Paper No. 7, dated March 7, 2000 has been entered and considered carefully.

2. The rejection of claims 1-7, 9, 11, 24-29 under 35 USC 103(a) over Christensen '743 in view of Berge et al. is maintained for reason of record.

Applicants argued that Christensen provided generic description and motivation for selecting the particular sulfonate is lacking. This is not persuasive for the reason of record. It was clearly delineated that the Berge reference not only particularly described the kind of sulfonate as the claims but also provided motivation since those particular sulfonates are FDA approved for marketing.

One in the pharmaceutical formulation filed is well provided with the skill of choosing a pharmaceutically acceptable acid to form the pharmaceutically acceptable salts. The FDA approval list further motivates one skilled in the art to pick and choose among the marketable salts with the knowledge that all salts will have analogous function.

Contrary to applicants's arguments concerning "hindsight construction", the salts are generically disclosed by Christensen and the motivation and suggestion for picking and choosing the sulfonates are provided by the prior art by Berge. Berge not only explicitly disclosed the mesylate and methylsulfate, but also suggested that they are FDA approved for marketing. Such disclosure expressly (Pro-mold and Tool v. Great Lakes Plastics, 37 USPQ2d 1626) guided one skilled in the art to choose the particular sulfonates for the generic teaching of Christensen, which are the claims. Therefore, the compounds, the salts and motivation for choosing are all found in the prior art. There is no element or part of applicant's's claimed subject matter which is not suggested or specifically disclosed by the prior art. The combination is proper without impermissible hindsight.

Art Unit: 1612

As it was explained in the previous office action, Krage '475 is not prior art but is "evidence" to show the inclusiveness for the term "pharmaceutically acceptable salts". In other words, the Krage reference with a comprehensive listing of the various acids is verifying that one having ordinary skill in the art would consider the Berge reference being inclusive in the Christensen disclosure since this is what ordinary skilled person considered to be inclusive for that term. A later publication can be employed to provide information for the state of the art (see MPEP 2164.05(a)) such as in the instant case, the Krage '475 provided the information that the Berge list would be considered to be inclusive in the term pharmaceutically acceptable acid addition salts of Christensen '743.

The argument with respect to solubility is irrelevant to the claims. Please note that the only information with respect to solubility of record is for the compound that has been proviso out by claim 1. No information on the instantly claimed compounds.

3. The rejection of claims 8, 15, 17 and 20-22 over Stemp '496, Drejer '574 or Christensen '743 is maintained for reason of record.

It was clearly recited in the previous office action of the particular acid and base being generically taught by the references. The only difference between the claimed process and the prior art process is that the particular disclosed sulfonic acid was not exemplified. With the example of a disclosed acid and the generic teaching of operability (see previous office actions for pages and lines), one having ordinary skill in the art in possession of the Stemp, Drejer or Christensen references would be motivated to carry out the exemplified process with all the acids generically embraced by the prior art disclosure, with the expectation that they would be operable analogously. Applicants have not provided any factual evidence that why the sulfonic acid being an optional choice for the exemplified process would have any unexpected results or inoperability. It is well settled that a reference may be relied upon for all that is would reasonably conveyed to one having ordinary skill in the art. In re Susi 169 USPQ 423, In re Lemin 141 USPQ 814.

Art Unit: 1612

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is (703) 308-4702.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

CCC/Chang

May 2, 2000

  
**CEILA CHANG**  
**PRIMARY EXAMINER**  
**GROUP 1200** 1625